K101782

510(k) SUMMARY

DEC 22 2010

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Company Registration Number	2023826
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Date Summary Prepared	January 4, 2011
Classification Name	Lens, Guide, Intraocular (Class I) – KYB 21 CFR 886.4300 Folders and Injectors, Intraocular Lens (IOL) (Class I) – MSS 21 CFR 886.4300
Common/Usual Name	Intraocular Lens Injector Cartridge
Device Trade Name	MicroSTAAR™ MSI Injector System Models: CQ, SFC 25, SFC 45

The primary devices used for comparison in this summary are: Epiphany Injector System (K090161) and MicroSTAAR™ Indigo Injector System (K073586).

Intended Use

The MicroSTAAR MSI Injector System is intended to fold and insert STAAR Surgical Company Collamer phakic and aphakic 1-piece and 3-piece Collamer® intraocular lenses for surgical placement in the human eye. The MSI Cartridges in this submission are just one component of the MicroSTAAR MSI Injector System.

The intended use of the MSI Cartridges in this submission are substantially equivalent to the intended use of the predicate devices K940593 (CQ cartridge FP), K980696 (SFC-45 FP), and K073586 (SFC-25 FP). Please refer to **Attachment 1** for a copy of the Directions for Use for the predicate devices which will be the same for the MSI Cartridges.

K101782

DEC 22 [illegible]

510(k) SUMMARY

Submitter Information:

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Company Registration Number: 2023826

Manufacturer/[illegible]:

STAAR Surgical Company
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Director of Regulatory Affairs
1911 Walker Avenue
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Date Summary Prepared: January 1, 2011

Classification Name: Lens, Guide, Intraocular; (Class II) per 21 CFR 886.4300; Folders and Injectors, Intraocular Lens (IOL); (Class II – MSS 21 CFR [illegible])

Common/Usual Name: Intraocular Lens Injector/Cartridge

Proprietary Name: STAAR EAPP[TM] Mini Injector System; Models: CO, SFC-15, SFC-45

The predicate devices used for comparison in this summary are: Epiphany Injector System (K[illegible]) and STAAR EAPP[TM] Micro Injector System (K073585).

A. Device Description

The STAAR EAPP Mini Injector System is intended to fold and insert STAAR's [illegible] one piece Collamer and 3 piece Collamer intraocular lenses for [illegible]. The MSI Cartridges in this submission are one component of the STAAR MSI Injector System.

The [illegible] of the MSI Cartridges in this submission are substantially equivalent to the [illegible] predicate [illegible] cartridge [illegible]. Please refer to Attachment 4 for a copy of the Directions for Use [illegible], which will be the same for the MSI Cartridges.

Description

The injector system is designed to facilitate the loading, folding and delivery of an intraocular lens (IOL) into the human eye through a small incision. The MicroSTAAR™ MSI injector System Cartridge utilizes three different cartridges for the insertion of an IOL lens. The three cartridges; CQ cartridge, SFC-45 cartridge and the SFC-25 cartridge are designed to facilitate a folded IOL lens for delivery. Each cartridge has a loading area which tapers down to a small tip, for the SFC-45 and SFC-25 cartridges, the lens loading area is flat and for the CQ cartridge the loading area is hinged. It is a component that is fabricated from polypropylene mixed with Glycerol Monostearate (GMS). Currently, the cartridge is cleared for fabrication from polypropylene mixed with GMS and is supplied sterile.

Technological Characteristics

The MicroSTAAR™ MSI injector System Cartridge has substantially equivalent technological characteristics to the predicate device. Refer to Table 1 in the following section, entitled Comparison Analysis, for a summation of technological characteristics such as design, specifications and materials.

Comparison Analysis

510(k)	MicroSTAAR Injector System K940593, K980696, K073586	Epiphany Injector System K090161 Epiphany	MicroSTAAR MSI Injector System Cartridges	Substantially Equivalent
Product Description	System is designed to facilitate the loading, folding and delivery of an intraocular lens (IOL) into the human eye through a small incision.	System is designed to facilitate the loading, folding and delivery of an intraocular lens (IOL) into the human eye through a small incision.	System is designed to facilitate the loading, folding and delivery of an intraocular lens (IOL) into the human eye through a small incision.	Same
Intended Use	Intended to fold and insert STAAR Surgical Company 1-piece or 3-piece Collamer intraocular lenses for surgical placement in the eye.	Intended to fold and insert STAAR Surgical Company 3-piece Silicone intraocular lenses for surgical placement in the eye.	Intended to fold and insert STAAR Surgical Company 1-piece and 3-piece Collamer intraocular lenses for surgical placement in the eye.	Same
Design	Single cartridge to be used in conjunction with appropriate injector system and 1-piece or 3-piece Collamer lenses for surgical placement of lens into eye.	A single component medical device used in conjunction with 3-piece silicone lenses for surgical placement in the eye.	Single cartridge to be used in conjunction with appropriate injector system and 1-piece or 3-piece Collamer lenses for surgical placement of lens into eye.	Same
Materials	Cartridge is manufactured from Polypropylene purchased from US Supplier.	Cartridge is manufactured from Polypropylene MG05 and Polypropylene MG03 purchased from Japan Supplier.	Cartridge is manufactured from Polypropylene MG05 and Polypropylene MG03 purchased from Japan Supplier.	Same
Mechanical Safety				
Manufacturing	Utilization of contract manufacturers and in-house processing at Monrovia facility	Utilization of contract manufacturers and in-house processing at the STAAR Japan facility	Utilization of contract manufacturers and in-house processing at the STAAR Japan facility, while molding process is still done by a US contractor.	Similar

MicroSTAAR™ (MSI) INJECTOR SYSTEM CARTRIDGES

510(k)	MicroSTAAR Injector System K940593, K980696, K073586	Epiphany Injector System K090161 Epiphany	MicroSTAAR MSI Injector System Cartridges	Substantially Equivalent
Operating Principle	The IOL is placed into the loading area and folded shut or gently pressed towards tip. Then cartridge is loaded onto the injector.	The cartridge is part of the Epiphany Injector. The lens is loaded into the cartridge, snapped shut, and pushed into pre-operative position.	Depending on the cartridge type, the IOL is either placed into the loading area and folded shut, or it is pressed forward towards the tip. Then cartridge is loaded onto the injector.	Same
Packaging	Cartridge is placed in tray, sealed with Tyvek lid and labeled. Tray is placed in Kraft paper pouch and then a foil pouch, and labeled again. US Packaging Supplier.	The Epiphany injector is placed into a tray, which is labeled. This unit is placed inside a pouch which is sealed. The sealed pouch is then put into a box with a package insert. Japanese Packaging Supplier.	Cartridge is placed in tray, sealed with Tyvek lid and labeled. Tray is placed in Kraft paper pouch. Japanese Packaging supplier.	Similar
Sterility	Sterile Ethylene Oxide (EtO) by Subcontractor	Sterile Ethylene Oxide (EtO) by STAAR Japan	Sterile Ethylene Oxide (EtO) by STAAR Japan	Same
Manufacturer	STAAR Surgical	STAAR Japan	STAAR Japan	Same

Table 1 – Summary of Design comparison for 21 CFR § 807.87(f)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB - 7 2011

STAAR Surgical Company
c/o Mr. Jack Coggan
Director of Regulatory Affairs
1911 Walker Avenue
Monrovia, CA 91016

Re: K101782
Trade/Device Name: MicroSTAAR Injector System Cartridges
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular lens guide
Regulatory Class: Class I, reserve
Product Code: MSS
Dated: December 2, 2010
Received: December 6, 2010

Dear Mr. Coggan:

This letter corrects our substantially equivalent letter of December 22, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101782

Device Name: MicroSTAAR™ Injector System Cartridge

Indications For Use:

The MicrSTAAR™ MSI Injector System is a device intended to fold and insert STAAR™ Surgical Company Collamer phakic and aphakic one-piece and three-piece Collamer® intraocular lenses for surgical placement in the eye.

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jennifer Brown

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K101782